IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Confirmation No.: 4777
Muhammed MAJEED et al.	Group Art Unit: 1655
Application No.: 10/710,778	Examiner: Patricia A. LEITH
Filed: August 2, 2004	Attorney Docket No.: 108064-00196

For: COMPOSITIONS AND METHODS FOR THE MANAGEMENT OF HYPERPROLIFERATIVE DERMATOLOGICAL CONDITIONS

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DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Muhammed Majeed, hereby declare that:

1. I am the Chairman of Sami Labs Limited ("Sami Labs"), the assignee of the above-identified patent application. The assignment was recorded on August 4, 2004 at reel 014971, frame 0986. I am also the Chairman and CEO of Sabinsa Corporation ("Sabinsa"), which is the marketing group of Sami Labs.
2. This Declaration presents data generated on behalf of Sami Labs comparing the effects on symptoms of plaque psoriasis of a combined treatment of oral Boswellia serrata extract and selenomethionine and topical Boswellia serrata extract, as in the present claims of the above-identified patent application, with alternative treatments including placebo, oral Boswellia serrata extract alone, a combination of oral Boswellia serrata extract alone and topical Boswellia serrata extract, and oral selenium alone.
3. Subjects having symptoms of plaque psoriasis received one of the following treatments:
    a. Treatment Group A (control) was orally administered placebo for 90 days;
    b. Treatment Group B was orally administered Boswellia serrata extract (400 mg boswellic acids three times per day) for 90 days;

c. Treatment Group C was orally administered Boswellia serrata extract (400 mg boswellic acids three times per day) and topically administered a cream having 5% Boswellia serrata extract three times a day for 90 days;
d. Treatment Group D was orally administered Boswellia serrata extract (400 mg boswellic acids three times per day) and L-selenomethionine (100 mcg elemental selenium per day), and topically administered a cream having 5% Boswellia serrata extract three times a day for 90 days;
e. Treatment Group E was orally administered L-Selenomethionine (100 mcg elemental selenium per day) for 90 days.

4. Psoriasis Area and Severity Index ("PASI") scores were measured in the treatment groups at baseline and at each visit by a scoring method as follows:
   a. Elements:
      i. Body regions as percent of Body Surface Area ("BSA") (Table 1)

Table 1

Body Region (code)	BSA (%)
Head (H)	10%
Trunk (T)	20%
Upper Extremities (U)	30%
Lower Extremities (L)	40%

      ii. Extent of body region affected (Table 2)

Table 2

Portion of Body Region Affected	Extent Indicator
0-5%	0
5-25%	1
25-45%	2
45-55%	3

55-75%	4
75-95%	5
95-100%	6

iii. Extent of psoriatic changes (Table 3)

Table 3

Changes in Psoriasis (code)	Extent
Erythema (E)	0-4
Infiltration (I)	0-4
Desquamation (D)	0-4

b. PASI Score =

i. = SUM (percent BSA in body region) * ((extent erythema (E) in region) + extent infiltration (I) in region) + (extent desquamation (D) in region)) * (extent of body region affected))

ii. = ((0.1 * ((erythema head) + (infiltration head) + (desquamation head) * (extent of head affected)) + ((0.2 * ((erythema trunk) + (infiltration trunk) + (desquamation trunk) * (extent of trunk affected)) + ((0.3 * ((erythema upper extremities) + (infiltration upper extremities) + (desquamation upper extremities) * (extent of upper extremities affected)) + ((0.4 * ((erythema lower extremities) + (infiltration lower extremities) + (desquamation lower extremities) * (extent of lower extremities affected))

iii. Interpretation:

1. Minimum Score = 0
2. Maximum Score = 72

c. A total number of 30 subjects were involved in the blinded study. Male and female subjects were treated with an oral formulation in the form of

tablets with or without a topical application in the form of a cream (in Treatment Groups C and D only), three times a day for 12 weeks.

d. The inclusion and exclusion criteria for selecting subjects were as follows:
    i. Inclusion Criteria:
        1. Subjects aged 18-65 years;
        2. Subjects with Mild to Moderate Psoriasis;
        3. Subjects who had not used corticosteroids or, if used corticosteroids before, with a one-month washout period; and
        4. subjects who had signed the informed consent form.
    ii. Exclusion Criteria:
        1. Subjects with more than 50% of body surface area covered by psoriasis lesions;
        2. Subjects on anticoagulant therapy;
        3. Subjects who had used immunosuppressive medication within the previous two months;
        4. Subjects with other skin lesions (actinic ketoses or lentigo) or photo damaged skin;
        5. Subjects who had used systemic or intralesional therapy or photo (chemo) therapy for psoriasis in the previous two months;
        6. Subjects with concomitant bacterial, fungal, or vital skin infections;
        7. Subjects who were pregnant or sexually active women who did not use contraception;
        8. Subjects who showed non-adherence to treatment;
        9. Subjects with a history of renal disease, hepatobiliary disease, malignancy, hypertension, or recurrent acute infection; and

10. Subjects with a history of any other evidence of severe illness or any other conditions that would make the subject, in the opinion of the investigator, unsuitable for the study.

5. Table 4 below discloses mean PASI scores.

Table 4

Treatment Group	Mean PASI Scores						
	Baseline	Visit 1	Visit 2	Visit 3	Final Visit	Change Between Baseline and Final	Change Between Baseline and Final After Subtracting the Placebo Effect
A	9.8	9.6	9.9	9.5	9.7	-0.1	n/a
B	10.3	10.0	9.8	9.9	9.2	-1.1	-1.0
C	10.8	9.2	8.5	8.3	8.3	-2.5	-2.4
D	10.5	4.2	4.2	4.2	4.5	-6.0	-5.9
E	9.4	9.4	9.2	8. 7	8.6	-0.8	-0.7

6. Table 4 discloses that Treatment Group D, treated with the novel method of the present claims, produced a significantly and beneficial reduction in mean PASI scores. The unexpected efficacy demonstrated in Treatment Group D was far beyond any expected additive effect of individual components (i.e., a 5.9 reduction in PASI scores in Treatment Group D between baseline and final scores after subtraction of the placebo effect, as compared to a 3.1 reduction in PASI scores after combining the effects seen in, for example, Treatment Groups C and E after subtraction of the placebo effect from each group). In contrast, Table 4 discloses that the reduction in PASI scores in Treatment Groups B, C, and E (i.e., oral Boswellia serrata extract alone or oral Boswellia serrata extract and topical Boswellia serrata extract or oral selenomethionine alone, respectively) were significantly lower.

7. Marker assays were also measured in each treatment group at baseline and at the final visit by standard biochemical methods. Serum Tumor Necrosis Factor Alpha ("TNF Alpha") and Vascular Endothelial Growth Factor ("VEGF") levels were measured using enzyme-linked immunosorbent assay (ELISA).

Prostaglandin E2 ("PGE2") and Leukotriene B4 ("LTB4") were similarly measured by immunoassays using commercially available kits.

8. Tables 5A-5D below disclose baseline and final results of the marker assays in each treatment group.

Table 5A*

Treatment Group	TNF Alpha (pg/ml)			
	Baseline	Final	Change Between Baseline and Final	Change Between Baseline and Final After Subtraction of Placebo Effect
A	10.34	9.78	-0.56	n/a
B	9.36	7.92	-1.44	-0.88
C	11.38	7.68	-3.70	-3.14
D	8.16	1.723	-6.44	-5.88
E	7.149	5.723	-1.426	-0.866

* n = 6 in each treatment group.

Table 5B*

Treatment Group	VEGF (pg/ml)			
	Baseline	Final	Change Between Baseline and Final	Change Between Baseline and Final After Subtraction of Placebo Effect
A	97.44	95.23	-2.21	n/a
B	89.72	87.65	-2.07	+0.14
C	73.74	78.32	+4.58	+6.79
D	117.75	58.15	-59.60	-57.39
E	70.99	147.09	+ 76.01	+78.22

* n = 6 in each treatment group.

Table 5C*

Treatment Group	PGE2 (pg/ml)			
	Baseline	Final	Change Between Baseline and Final	Change Between Baseline and Final After Subtraction of Placebo Effect
A	1096.98	998.78	-98.20	n/a
B	1142.26	1001.25	-141.01	-42.81
C	1532.95	1392.86	-140.09	-41.89
D	907.37	558.21	-349.16	-250.96
E	896.46	103.58	-792.88	-694.68

* n = 6 in each treatment group.

Table 5D*

Treatment Group	LTB4 (pg/ml)			
	Baseline	Final	Change Between Baseline and Final	Change Between Baseline and Final After Subtraction of Placebo Effect
A	498.47	487.24	-11.23	n/a
B	286.23	269.86	-16.37	-5.14
C	161.42	152.26	-9.16	-5.14
D	518.41	242.65	-275.76	-264.53
E	320.91	500.14	+179.23	+190.46

* n = 6 in each treatment group.

9. Tables 5A, 5B, and 5D disclose an unexpected and substantial reduction in TNF Alpha, VEGF, and LTB4 in Treatment Group D, as compared to the other treatment groups. As to PGE2 in Table 5C, Treatment Group D showed an unexpected and substantial reduction as compared to Treatment Groups B and C. As such, Tables 5A-5D further substantiate the data in Table 4, as the biochemical assays of markers TNF Alpha, VEGF, PGE2 and LKB4 showed an unexpected and substantial decrease in Treatment Group D for these markers.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent(s) issuing therefrom.

Muhammed Majeed

Dr. Muhammed Majeed

Date: March 6, 2008